



UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|-----------------|-------------|----------------------|---------------------|------------------|
| 09/740,393 | 12/18/2000 | Manfred Weigle | 395D US | 3200 |

7590 09/24/2004

David L. Berstein
ARIAD Pharmaceuticals, Inc.
26 Landsdowne Street
Cambridge, MA 02139-4234

| |
|----------|
| EXAMINER |
|----------|

BERCH, MARK L

| | |
|----------|--------------|
| ART UNIT | PAPER NUMBER |
|----------|--------------|

1624

DATE MAILED: 09/24/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

| | | | |
|--|--------------------------------------|---------------------------------------|--|
| <p align="center">Office Action Summary</p> | Application No. 09/740,393 | Applicant(s) WEIGELE ET AL. | |
| | Examiner Mark L. Berch | Art Unit 1624 | |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 04 August 2004.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 22-26,29-34,36,39,40 and 47-52 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 22-26,29-34,36,39,40 and 47-52 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
 Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
 Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
 a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

Art Unit: 1624

DETAILED ACTION*Continued Examination Under 37 CFR 1.114*

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 8/4/2004 has been entered.

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 22-26, 29-34, 36, 39-40, 47-52 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-174 of copending Application No. 09/740653. Although the conflicting claims are not identical, they are not patentably distinct from each other because the claims of the two cases are broadly overlapping.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 22-26, 29-34, 36, 39-40, 47-52 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

1. Claim 36 needs to end in a period.
2. Claim 36 definition for R3 has a semicolon after the first choice but not the others.
Are there two lists present?
3. The term "acyl" (e.g. claim 25, line 4, and as part of "acylamino" seen in e.g. R3 of claim 36) is indefinite. What does the stem look like, i.e. if the acyl is e.g. RC(O), what is R? The traverse is unpersuasive. The Morrison reference says "R may be alkyl or aryl"; Hawley's is silent on what R is, as are the remarks. Thus, it is not clear whether just alkyl and aryl are intended, or something more, and if there is more, what?
4. Claim 5, second from last line of page 4, has "sulfate, sulfonate, sulfate, sulfonate," which is duplicative. This occurs in other places where the variable R3 occurs.
5. In claim 5, Sulfonate makes no sense. It is a divalent radical but is used for a monovalent moiety.
6. The term "sulfate" (seen in e.g. R3 of claim 36) is divalent; as was sated previously, sulfate is $-\text{OS}(\text{O})_2\text{O}-$ i.e. SO_4^- . The traverse is unpersuasive. Applicants have

misdrawn the group as $-\text{OSO}_3\text{H}$, but that is NOT the sulfate but the bisulfate.

Applicants have supplied the Webster reference, but that just supports the examiners position, since that gives the SO_4^- . To refute applicant's position, there is cited The American Heritage® Dictionary of the English Language: Fourth Edition (2000) entry for bisulfate which says specifically that HSO_4 is the bisulfate.

7. A Sulfonate is $-\text{S}(\text{O})_2\text{O}-$, divalent, in which the left bond attaches to a stem and the right is the bond of attachment, or both can be bonds of attachment. The traverse is unpersuasive. The $-\text{SO}_3\text{H}$ group is the sulfo group, not the sulfonate group. The reference cited is of no value, because page 689 does not give this $-\text{SO}_3\text{H}$ term at all. The reference "SULFO GROUP" is cited to show that this is the sulfo group. Further, the term "sulfo" is used in the specification already (see e.g. page 14, line 8) so that the use of a different term sulfonate clearly implies that something other than sulfo was intended.
8. Similarly, the terms sulfonyl i.e. $-\text{SO}_2-$ and sulfoxido i.e. $-\text{S}(\text{O})-$ are also divalent and thus are not possible as substituents.
9. Claim 36 lacks definition for Y and R1. This has not been fixed. There is also no definition for G, R2, K, M, M_Y and x.
10. Claim 49 makes no sense. It defines a variable which does not exist in any of these claims.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Mark L. Berch whose telephone number is 571-272-0663. The examiner can normally be reached on M-F 7:15 - 3:45.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Mukund Shah can be reached on (571)272-0674. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



Mark L. Berch
Primary Examiner
Art Unit 1624

9/22/04